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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------------|------------------------|
| 10/530,866 | 04/11/2005 | John-Olov Jansson | JANSSON7 | 2241 |
| 1444 7590 05/21/2007 BROWDY AND NEIMARK, P.L.L.C. 624 NINTH STREET, NW SUITE 300 WASHINGTON, DC 20001-5303 | | | EXAMINER LUKTON, DAVID | |
| | | | ART UNIT 1654 | PAPER NUMBER |
| | | | MAIL DATE 05/21/2007 | DELIVERY MODE PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/530,866

Applicant(s)

JANSSON, JOHN-OLOV

Examiner

David Lukton

Art Unit

1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 February 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10, 14, 15, 18, 20, 22, 27, 28 and 30 is/are pending in the application.
- 4a) Of the above claim(s) 18 and 20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10, 14, 15, 22, 27, 28 and 30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

Claims 1-10, 14, 15, 18, 20, 22, 27, 28 & 30 remain pending.

Applicants' election of "G2" is acknowledged (a method for preventing or treating cachexia in a gastrectomized individual). The previous species elections remain in force as well (response filed 10/23/06 and 1/9/07).

Claims 18 and 20 are withdrawn from consideration; claims 1-10, 14, 15, 22, 27, 28 & 30 are examined in this Office action.



35 U.S.C. §101 reads as follows:

"Whoever invents or discovers any new and useful process, machine, manufacture or composition of matter or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title".

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it in such full, clear, concise and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-10, 14, 15, 22, 27, 28 & 30 are rejected under 35 USC §101 because the claimed invention is not supported by ~~either~~ a well established utility.

The claims are drawn to a method of "preventing" loss of body weight, and to "prophylaxis" of cachexia. However, applicants have not even attempted to show that this might be true.

Even if it is true that ghrelin can mitigate loss of body weight, or that ghrelin can mitigate the state of cachexia, it does not follow therefrom that outright prevention can be achieved.

Claims 1-10, 14, 15, 22, 27, 28 & 30 are also rejected under 35 USC §112 first paragraph. Specifically, since the claimed invention is not supported by a well established utility for the reasons set forth above, one skilled in the art would not know how to use the claimed invention.

✦

Claims 15, 22 are rejected under 35 U.S.C. §112 second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 15, the term “the solvent” lacks antecedent basis.

In claim 22, the term “pulmonal” is misspelled.

✦

The following is a quotation of 35 USC §103 which forms the basis for all obviousness rejections set forth in the Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.

Patentability shall not be negated by the manner in which the invention was made. Subject matter developed by another person, which qualifies as prior art only under subsection (f) and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made, absent any evidence to the contrary. Applicant is advised of the

obligation under 37 C.F.R. 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103.

Claims 1, 14, 15, 22, 27, 28, 30 are rejected under 35 U.S.C. §103 as being unpatentable over (a) Zittel T. (*American Journal of Surgery* 169(2), 265-70, 1995) or (b) Saidi F (*Journal of the American College of Surgeons* 189(3), 259-68, 1999) or (c) Liedman B. (*The British Journal of Surgery* 85(4), 542-7, 1998) in view of (i) Wren A. M. (*The Journal of Clinical Endocrinology and Metabolism* 86(12), pp. 5992-95, 2001) or (ii) Asakawa, A., et al., (*Gastroenterology* 120, 337-345, 2001).

Each of the primary references (Zittel, Saidi, Liedman) discloses that gastrectomy causes weight loss. Each of the secondary references (Wren and Asakawa) discloses that ghrelin stimulates appetite.

Thus, it would have been obvious to administer ghrelin to reverse the adverse effects of weight loss caused by the gastrectomy.



Claims 1-10 are rejected under 35 U.S.C. §103 as being unpatentable over (a) Zittel T. (*American Journal of Surgery* 169(2), 265-70, 1995) or (b) Saidi F (*Journal of the American College of Surgeons* 189(3), 259-68, 1999) or (c) Liedman B. (*The British Journal of Surgery* 85(4), 542-7, 1998) in view of (i) Wren A. M. (*The Journal of Clinical Endocrinology and Metabolism* 86(12), pp. 5992-95, 2001) or (ii) Asakawa, A.,

et al., (*Gastroenterology* **120**, 337-345, 2001) further in view of Kojima, M. (Nature 402 (6762), 656-660, 1999).

As indicated above, each of the primary references (Zittel, Saidi, Liedman) discloses that gastrectomy causes weight loss. Each of the secondary references (Wren and Asakawa) discloses that ghrelin stimulates appetite. Kojima provides the sequence of ghrelin.

Thus, the claims are rendered obvious.



Claims 1-10 are rejected under 35 U.S.C. §103 as being unpatentable over (a) Zittel T. (*American Journal of Surgery* 169(2), 265-70, 1995) or (b) Saidi F (*Journal of the American College of Surgeons* 189(3), 259-68, 1999) or (c) Liedman B. (*The British Journal of Surgery* 85(4), 542-7, 1998) in view of (i) Wren A. M. (*The Journal of Clinical Endocrinology and Metabolism* **86**(12), pp. 5992-95, 2001) or (ii) Asakawa, A., et al., (*Gastroenterology* **120**, 337-345, 2001) further in view of Hosoda, H. (*J. Biol. Chem.* **278**(1), 64-70, 2003)

As indicated above, each of the primary references (Zittel, Saidi, Liedman) discloses that gastrectomy causes weight loss. Each of the secondary references (Wren and Asakawa) discloses that ghrelin stimulates appetite.

In response to this ground of rejection, applicants are likely to argue that they are entitled to the priority date of 10/10/02. If this is going to be the argument, applicants

will be requested to point to the page and line number(s) where descriptive support can be found for the peptides disclosed in Hosoda.



No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Lukton whose telephone number is 571-272-0952. The examiner can normally be reached Monday-Friday from 9:30 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang, can be reached at (571)272-0562. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.



**DAVID LUKTON, PH.D.
PRIMARY EXAMINER**